REMARKS

Status of the claims

Claims 9, 21 and 22 are pending in the application.

Rejection under 35 U.S.C.§112, 1st paragraph

Claims 9, 21 and 22 have been rejected under 35 U.S.C.§112, as lacking sufficient written description in the originally filed specification. More specifically, the Examiner asserts that the recitation in the claims of the feature of "further measuring the efficacy of any chemical compound, which is identified as having the ability to block the C1C-7 chloride channel, in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of bone", lacks support in the originally filed specification, i.e. is new matter. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

The CAFC in *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989) clearly held that the test for whether a recited feature is supported by the original disclosure, is not whether there is an explicit recitation in the specification of the words used in the claims, but rather whether the feature would be clear to one skilled in the art when reading the claims, not just in view of the specification, but also in view of the known art at the time of the invention. *Id at 1651.* The court in *Wright* further reiterated that "the claimed subject matter need not be described in *haec verba* in the specification in order for that specification to satisfy the description requirement". *Id at 1650.*

That the present invention necessarily includes the feature of "further measuring the efficacy of any chemical compound, which is identified as having the ability to block the C1C-7 chloride channel, in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of bone" would be readily apparent to one skilled in the art upon reading the originally filed specification.

The present invention is defined in the specification, at lines 6-7 of page 1, as follows: "The present invention relates to a method for screening compounds for activity in treating an osteoclast related bone disease." The title of the invention is the same. On page 2 of the specification, the first and second aspects of the invention are defined as:

Thus, in its first aspect, the invention relates to a method for screening a chemical

compound for activity in the treatment, prevention or alleviation of an osteoclast related bone disease in a subject.

In its second aspect, the invention relates to a drug development method.

Thus, it is readily apparent from the specification that the entire focus of the invention is drug development. The overall object of the instant invention is to provide more effective and selective compounds with fewer side effects for the treatment of patients with an osteoclast related bone disease, such as osteoporosis (see page 2, lines 9-11).

It would be readily apparent to one skilled in the art of drug development and pharmacology that in order to measure the efficacy of any chemical compound, it must be established (1) how effective and selective the compounds block the C1C-7 channel as well as (2) the degree of side effects the administration of the compounds causes.

The efficiency and the selectivity of the compounds are determined, for instance, as specifically described in Examples 3 and 4 or as mentioned on page 6, lines 21-34, in the specification. A cell model or an animal model on how to determine whether the new compounds of the instant invention cause side effects when administered to a patient is not specifically described in the instant application. However, the need to perform such tests as a part of the invention would be both readily apparent to one skilled in the art and the ability to do so lies well within the skills of an ordinary practitioner. Such studies can only be characterized as routine experiments, which are always performed before a conclusion regarding efficacy can be made and before authorization for placing a compound as a drug on the market will be granted.

Furthermore, according to the claims, as filed, the instant invention (as a whole) relates to:

- a method for screening a chemical compound for activity in the treatment, prevention or alleviation of an osteoclast related disease in a subject by measuring the ability of the compound to block the selected chloride channels, (claim 1 as filed),

- the use of said compound identified as a blocker of a chloride channel for the manufacture of a medicament for the treatment, prevention or alleviation of an osteoclast related disease a subject (claim 5 as filed), and

- a method for the treatment, prevention or alleviation of an osteocast related disease a subject comprising administering to said subject a therapeutically effective amount of a compound identified as a blocker of a chloride channel (claim 6 as filed).

As mentioned above, the degree of side effects caused by a compound must be determined before a compound can be used for the manufacture of a medicament for treatment of a disease and/or before a compound can be in used the treatment of a disease. Consequently, the further step of measuring the efficacy of the chemical compounds has been inherently disclosed in the application as filed.

As such, the recitation in the claims of "further measuring the efficacy of any chemical compound, which is identified as having the ability to block the C1C-7 chloride channel, in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of bone" is not new matter and is supported by the disclosure as originally filed. Withdrawal of the rejection is therefore respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, PhD, Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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